



PB 99 of 2024

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2024

National Health Act 1953

I, NIKOLAI TSYGANOV, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health and Aged Care, delegate of the Minister for Health and Aged Care, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 27 September 2024

NIKOLAI TSYGANOV
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division

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1 Name

- (1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2024*.
- (2) This instrument may also be cited as PB 99 of 2024.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. <i>The whole of this instrument</i>	<i>1 October 2024</i>	<i>1 October 2024</i>

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 100(2) of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Highly Specialised Drugs Program) Special Arrangement 2021 (PB 27 of 2021)

[1] Schedule 1, entry for Abacavir with Lamivudine

omit:

	ABACAVIR/LAMIVUDI NE 600/300 SUN	C4527 C4528	60	5
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[2] Schedule 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Adalicip]

insert:

	Hadlima	C12120 C14061 C14063 C14064 C14107 C14136	See Schedule 2	See Schedule 2
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[3] Schedule 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe [Brand: Adalicip]

insert:

	Hadlima	C12120 C14061 C14063 C14064 C14107 C14136	See Schedule 2	See Schedule 2
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[4] Schedule 1, entry for Adalimumab in each of the forms: Injection 40 mg in 0.8 mL pre-filled pen; and Injection 40 mg in 0.8 mL pre-filled syringe

omit:

	Idacio	C12120 C14061 C14063 C14064 C14107 C14136	See Schedule 2	See Schedule 2
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[5] Schedule 1, entry for Benralizumab

(a) omit from the column headed “Circumstances”: C15383 C15444

(b) insert in numerical order in the column headed “Circumstances”: C15871 C15884

[6] Schedule 1, entry for Dupilumab in the form Injection 200 mg in 1.14 mL single dose pre-filled syringe

(a) omit from the column headed "Circumstances": **C15341**

(b) omit from the column headed "Circumstances": **C15433**

(c) insert in numerical order in the column headed "Circumstances": **C15886 C15924**

[7] Schedule 1, entry for Entecavir in the form Tablet 0.5 mg (as monohydrate)

omit:

	Entecavir Mylan	C4993 C5036	60	5
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[8] Schedule 1, after entry for Lamivudine in the form Tablet 150 mg [Brand: Lamivudine Alphapharm]

insert:

	Lamivudine Viatris	C4454 C4512	120	5
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[9] Schedule 1, after entry for Lenalidomide in the form Capsule 15 mg [Brand: Revlimid]

insert:

Capsule 20 mg	Oral	Lenalide	C13782 C13785 C13786 C13787 C13803 C13805 C13811 C13812 C13813 C14362	See Schedule 2	See Schedule 2
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[10] Schedule 1, entry for Mepolizumab in the form Injection 100 mg in 1 mL single dose pre-filled pen

(a) omit from the column headed "Circumstances": **C15344**

(b) omit from the column headed "Circumstances": **C15400**

(c) insert in numerical order in the column headed "Circumstances": **C15849 C15873**

[11] Schedule 1, entry for Omalizumab in each of the forms: Injection 75 mg in 0.5 mL single dose pre-filled syringe; and Injection 150 mg in 1 mL single dose pre-filled syringe

(a) omit from the column headed "Circumstances": **C15346**

(b) omit from the column headed "Circumstances": **C15401**

(c) *insert in numerical order in the column headed "Circumstances": C15846 C15870*

[12] **Schedule 1, after entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg [Brand: TENOFOVIR/EMTRICITABINE 300/200 ARX]**

insert:

Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A)	Oral	Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA)	C6985 C6986	60	5
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[13] **Schedule 1, entry for Tenofovir with emtricitabine**

omit:

Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg	Oral	Tenofovir EMT GH	C6985 C6986	60	5
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[14] **Schedule 1, entry for Vedolizumab**

omit from the column headed "Circumstances": C9738 C9771 C12080 C12083 C12135 C12137 C12179 C12219 C12220 C12221

substitute: C15838 C15839 C15840 C15844 C15882 C15909 C15910 C15921 C15923 C15930 C15933

[15] **Schedule 2, entry for Benralizumab [Maximum quantity: 1; Maximum repeats: Sufficient for 32 weeks of treatment]**

(a) *omit from the column headed "Circumstances": C15383 C15444*

(b) *insert in numerical order in the column headed "Circumstances": C15871 C15884*

[16] **Schedule 2, entry for Dupilumab [Maximum quantity: 1 pack; Maximum repeats: Sufficient for 32 weeks of treatment]**

(a) *omit from the column headed "Circumstances": C15341*

(b) *omit from the column headed "Circumstances": C15433*

(c) *insert in numerical order in the column headed "Circumstances": C15886 C15924*

[17] **Schedule 2, entry for Mepolizumab [Maximum quantity: 1; Maximum repeats: Sufficient for 32 weeks of treatment]**

insert in numerical order in the column headed "Circumstances": C15849 C15873

[18] Schedule 2, entry for Omalizumab [Maximum quantity: 1; Maximum repeats: Sufficient for 32 weeks of treatment]

- (a) omit from the column headed "Circumstances": **C15346**
- (b) omit from the column headed "Circumstances": **C15401**
- (c) insert in numerical order in the column headed "Circumstances": **C15846 C15870**

[19] Schedule 2, entry for Vedolizumab

substitute:

Vedolizumab	C15930	1	0
	C15838 C15839 C15844 C15882 C15910 C15921 C15923 C15933	1	2
	C15840 C15909	1	Sufficient for treatment for 24 weeks

[20] Schedule 3, entry for Benralizumab

- (a) omit:

	C15383		<p>Uncontrolled severe asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p>	Compliance with Written Authority Required procedures
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		<p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (b) details (date and duration of treatment) of prior biological medicine treatment; and (c) eosinophil count and date; and (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, 	
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		adverse event to prior therapy).	
	C15444	<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p>	Compliance with Written Authority Required procedures

		<p>Optimised asthma therapy includes:</p> <p>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;</p> <p>AND</p> <p>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p>	
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		<p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and</p> <p>(b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and</p> <p>(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(d) the eosinophil count and date; and</p> <p>(e) Asthma Control Questionnaire (ACQ-5) score.</p>	
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(b) *insert in numerical order after existing text:*

	C15871	<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved</p>	Compliance with Written Authority Required procedures
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		<p>PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased</p>	
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		<p>for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.</p> <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and (b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved 	
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			<p>Product Information; and</p> <p>(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(d) the eosinophil count and date; and</p> <p>(e) Asthma Control Questionnaire (ACQ-5) score.</p>	
	C15884		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p>	Compliance with Written Authority Required procedures

		<p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and</p> <p>(b) details (date and duration of treatment) of prior biological medicine treatment; and</p> <p>(c) eosinophil count and date; and</p> <p>(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p> <p>(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
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[21] Schedule 3, entry for Dupilumab

(a) omit:

	C15341	<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p>	Compliance with Written Authority Required procedures
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		<p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400</p>	
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		<p>mg as an initial dose, followed by 200 mg every 2 weeks thereafter.</p> <p>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and</p> <p>(b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and</p> <p>(c) if applicable, the eosinophil count and date; and</p> <p>(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p> <p>(e) if applicable, the IgE result and date; and</p> <p>(f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
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(b) omit:

	C15433	<p>Uncontrolled severe asthma</p> <p>Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p>	Compliance with Written Authority Required procedures
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		<p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;</p> <p>AND</p> <p>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or</p>	
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		<p>intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.</p> <p>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p>	
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			<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and</p> <p>(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and</p> <p>(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(d) Asthma Control Questionnaire (ACQ-5) score; and</p> <p>(e) if applicable, the eosinophil count and date; and</p> <p>(f) if applicable, the IgE result and date.</p>	
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(c) insert in numerical order after existing text:

	C15886		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND</p>	Compliance with Written Authority Required procedures
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		<p>Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.</p> <p>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and 	
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			<p>(b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and</p> <p>(c) if applicable, the eosinophil count and date; and</p> <p>(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p> <p>(e) if applicable, the IgE result and date; and</p> <p>(f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
	C15924		<p>Uncontrolled severe asthma</p> <p>Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR</p>	Compliance with Written Authority Required procedures

		<p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4</p>	
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		<p>biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.</p> <p>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and</p> <p>(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and</p> <p>(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(d) Asthma Control Questionnaire (ACQ-5) score; and</p> <p>(e) if applicable, the eosinophil count and date; and</p> <p>(f) if applicable, the IgE result and date.</p>	
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[22] Schedule 3, entry for Mepolizumab

insert in numerical order after existing text:

	C15849	<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with</p>	<p>Compliance with Written Authority Required procedures</p>
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		<p>severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p>	
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		<p>(ii) A pharmacist, nurse or asthma educator.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and</p> <p>(b) details (date and duration of treatment) of prior biological medicine treatment; and</p> <p>(c) eosinophil count and date; and</p> <p>(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p> <p>(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
	C15873	<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the</p>	Compliance with Written Authority Required procedures

		<p>management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided,</p>	
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		<p>the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and</p> <p>(b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and</p> <p>(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(d) the eosinophil count and date; and</p> <p>(e) Asthma Control Questionnaire (ACQ-5) score.</p>	
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[23] Schedule 3, entry for Omalizumab

(a) *omit:*

	C15346	Uncontrolled severe asthma Initial treatment - Initial 2 (Change of treatment)	Compliance with Written Authority Required
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		<p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.</p>	procedures
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		<p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and</p> <p>(b) details (date and duration of treatment) of prior biological medicine treatment; and</p> <p>(c) the IgE results and date; and</p> <p>(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p> <p>(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
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(b) omit:

	C15401	<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as</p>	Compliance with Written Authority Required procedures
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		<p>a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;</p> <p>AND</p> <p>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased</p>	
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		<p>for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised 	
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			asthma therapy (date and treatment); and (d) the IgE result and date; and (e) Asthma Control Questionnaire (ACQ-5) score.	
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(c) insert in numerical order after existing text:

	C15846		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in</p>	Compliance with Written Authority Required procedures
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		<p>the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p>	
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		<p>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and</p> <p>(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and</p> <p>(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(d) the IgE result and date; and</p> <p>(e) Asthma Control Questionnaire (ACQ-5) score.</p>	
	C15870	<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more</p>	Compliance with Written Authority Required procedures

		<p>than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (b) details (date and duration of treatment) of prior biological medicine treatment; and 	
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			(c) the IgE results and date; and (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).	
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[24] Schedule 3, entry for Vedolizumab

substitute:

Vedolizumab	C15838		<p>Severe Crohn disease</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND</p> <p>Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR</p> <p>Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below;</p>	Compliance with Written Authority Required procedures
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		<p>OR</p> <p>Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.</p> <p>Patient must be at least 18 years of age.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) details of the proposed prescription; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and</p> <p>(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iv) the date of the most recent clinical assessment.</p> <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:</p> <p>(a) patient must have evidence of intestinal inflammation;</p> <p>(b) patient must be assessed clinically as being in a high faecal output state;</p> <p>(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.</p> <p>Evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time</p>	
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		<p>of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C15839	<p>Severe Crohn disease</p> <p>Continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR</p> <p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction; AND</p>	Compliance with Written Authority Required procedures

		<p>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR</p> <p>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) details of the proposed prescription; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or</p> <p>(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and</p> <p>(iii) the date of clinical assessment.</p> <p>All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of</p>	
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			<p>the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>	
	C15840		<p>Severe Crohn disease</p> <p>Balance of supply</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.</p>	Compliance with Authority Required procedures
	C15844		<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p>	Compliance with Written Authority Required procedures

		<p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; OR</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).</p> <p>Patient must be at least 18 years of age.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(a) details of the proposed prescription; and</p> <p>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and</p>	
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		<p>submitted no later than 4 weeks from the date of completion of treatment.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p>	
	C15882	<p>Severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR</p> <p>Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR</p> <p>Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is</p>	Compliance with Written Authority Required procedures

		<p>no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) details of the proposed prescription; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of</p>	
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			<p>that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C15909		<p>Moderate to severe ulcerative colitis</p> <p>Balance of supply</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.</p>	Compliance with Authority Required procedures
	C15910		<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological</p>	Compliance with Written Authority Required procedures

		<p>medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.</p> <p>Patient must be at least 18 years of age.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(a) details of the proposed prescription; and</p> <p>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.</p> <p>Up to a maximum of 2 repeats will be authorised.</p> <p>Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted</p>	
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		<p>following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p>	
	C15921	<p>Severe Crohn disease</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) details of the proposed prescription; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or</p> <p>(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to</p>	Compliance with Written Authority Required procedures

		<p>therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and</p> <p>(iii) the date of clinical assessment; and</p> <p>(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.</p> <p>If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
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	C15923	<p>Moderate to severe ulcerative colitis</p> <p>Continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR</p> <p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction; AND</p> <p>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.</p> <p>Up to a maximum of 2 repeats will be authorised.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of</p>	Compliance with Authority Required procedures
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			the first application under a new cycle under the Initial 3 treatment restriction.	
	C15930		<p>Severe Crohn disease</p> <p>Initial treatment - Initial 4 (additional dose at week 10)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received prior PBS-subsidised treatment with this drug for this condition in this treatment cycle; AND</p> <p>Patient must have received 3 doses of initial treatment under either (i) initial 1, (ii) initial 2, (iii) initial 3; AND</p> <p>Patient must not have achieved an adequate response to this drug after a total of 3 doses of initial treatment under either (i) initial 1, (ii) initial 2, (iii) initial 3 under this restriction; AND</p> <p>The treatment must not exceed a total of 4 doses to be administered at weeks 0, 2, 6 and 10 under the initial treatment phase.</p> <p>Patient must be at least 18 years of age.</p> <p>A maximum quantity and number of repeats to provide for an additional dose of this drug consisting of one vial of 300 mg, with one dose to be administered at week 10, will be authorised.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted prior to 10 weeks and a second assessment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>An adequate response to this drug defined as:</p> <p>a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or</p> <p>(a) an improvement of intestinal inflammation as demonstrated by:</p> <p>(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no</p>	Compliance with Authority Required procedures

		<p>greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or</p> <p>(ii) faeces: normalisation of lactoferrin or calprotectin level; or</p> <p>(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or</p> <p>(b) reversal of high faecal output state; or</p> <p>(c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.</p>	
	C15933	<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND</p> <p>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR</p> <p>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR</p> <p>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; OR</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).</p> <p>Patient must be at least 18 years of age.</p> <p>Application for authorisation of initial treatment must be in writing and must include:</p> <p>(a) details of the proposed prescription; and</p> <p>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:</p>	Compliance with Written Authority Required procedures

		<p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.</p> <p>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p>	
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